

Appl. No. 09/868,243

Amendment dated: August 18, 2004

Reply to OA of: May 18, 2004

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-39(canceled).

40(new). An oral vaccine composition against diarrhea caused by enterotoxigenic *E. coli*, which comprises at least 100 µg of at least three different types of colonization factor antigens (CFAs) selected from the group consisting of CFA I, CFA II (CS1, CS2 and CS3) and CFA IV (CS4, CS5 and CS6), on killed *E. coli* lacking the gene encoding the heat labile enterotoxin (LT), together with the B-subunit of cholera toxin (CTB), and a physiologically acceptable vehicle, wherein heat stable enterotoxin (ST) of said *E. coli* is removed from said antigens if present.

41(new). The oral vaccine according to claim 40, wherein the vaccine comprises five enterotoxigenic *E. coli* (ETEC) bacterial strains.

42(new). The oral vaccine according to claim 40, wherein the vaccine comprises:

- (i) An enterotoxigenic *E. coli* (ETEC) strain expressing CFA/I (SBL101),
- (ii) An enterotoxigenic *E. coli* (ETEC) strain expressing CFA/II (CS1) (SBL106),
- (iii) An enterotoxigenic *E. coli* (ETEC) strain expressing CFA/II (CS2 + CS3) (SBL107),
- (iv) An enterotoxigenic *E. coli* (ETEC) strain expressing CFA/IV (CS4 + CS6) (SBL104); and
- (v) An *E. coli* (ETEC) strain expressing CFA/IV (CS5 + CS6) (SBL105).

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43(new). The oral vaccine according to claim 41, wherein the vaccine comprises:

- (i) An enterotoxigenic *E. coli* (ETEC) bacterial strain expressing CFA/I (SBL101),
- (ii) An enterotoxigenic *E. coli* (ETEC) bacterial strain expressing CFA/II (CS1) (SBL106),
- (iii) An enterotoxigenic *E. coli* (ETEC) bacterial strain expressing CFA/II (CS2 + CS3) (SBL107),
- (iv) An enterotoxigenic *E. coli* (ETEC) bacterial strain expressing CFA/IV (CS4 + CS6) (SBL104); and
- (v) An *E. coli* (ETEC) bacterial strain expressing CFA/IV (CS5 + CS6) (SBL105).

44(new). The oral vaccine according to claim 40, wherein the vaccine comprises at least 0.5 mg of CTB, and the vehicle is a buffer solution.

45(new). The oral vaccine according to claim 44, wherein the vaccine comprises 100 to 300 µg of each type of CFA, and 0.5 to 2.0 mg of CTB.

46(new). The oral vaccine according to claim 45, wherein the vaccine comprises 200 µg of CFA/I, 200 µg of CS1, 150 µg of CS2, 200 µg of CS4 and 150 µg of CS5, and 1.0 mg of CTB, and the buffer solution is phosphate buffered saline solution.

47(new). The oral vaccine according to any one of claims 40 and 41-46, wherein the CTB is recombinant CTB (rCTB).

48(new). The oral vaccine according to claim 47, wherein 1 mg of r CTB is used.